

## REMARKS

This response addresses the Office Action dated July 12, 2007. Claims 1-46 are pending. Of these, claims 39-46 have been withdrawn from further consideration pursuant to a restriction requirement.

### **Rejection under § 112**

The Examiner rejected claims 2-26 under 35 U.S.C. § 112, second paragraph, as being indefinite.

#### *Claim 2*

Independent apparatus claim 1 recites a prosthesis system to replace a natural facet joint between adjoining inferior and superior vertebral bodies. The prosthesis system comprises a caudal prosthesis accommodating fixation to the inferior vertebral body at or near a pedicle and without support by a lamina, including an artificial caudal facet joint structure adapted and configured to replace all or a portion of a caudal portion of the natural facet joint, and a cephalad prosthesis accommodating fixation to the superior vertebral body at or near a pedicle and without support by a lamina, including an artificial cephalad facet joint structure adapted and configured to replace all or a portion of a cephalad portion of the natural facet joint and to articulate with the artificial caudal facet joint structure, thereby forming an artificial facet joint between the adjoining vertebral bodies. Claim 2 depends from claim 1 and further limits the structure recited in claim 1 by requiring that the artificial caudal facet joint structure be adapted and configured to replace a natural articular process of a caudal portion of the natural facet joint on the inferior vertebral body.

With respect to claim 2, the Examiner stated that “it is not clear how the structure of the device is further defined (as illustrated in elected figure 24) by the function of ‘adapted and configured to replace a natural articular process.’” (Office Action, p. 3). The meaning of this limitation, however, is clear from a comparison of the language of the two claims. In claim 1, the artificial caudal facet joint structure is adapted and configured to replace *all or a portion of* a caudal portion of the natural facet joint. Claim 2 is more limited: In the prosthesis system of claim 2, the artificial caudal facet joint structure is adapted and configured to replace *a natural*

*articular process* of a caudal portion of a natural facet joint. A skilled artisan would understand that a natural articular process of a caudal portion of a facet joint (as recited in claim 2) is different than all or a portion of a caudal portion of a natural facet joint (as recited in claim 1). This reason for the Examiner’s rejection of claim 2 therefore cannot sustain a rejection under § 112, second paragraph.

The Examiner’s second reason is that “the structure as set forth in claim 1 and as illustrated in figure 36 is not further modified by the method steps of claim 2.” Claim 2 is an apparatus claim, however, not a method claim. This portion of the Examiner’s rejection therefore makes no sense and appears to be an error. Applicant respectfully requests the Examiner to either clarify or withdraw this portion of his rejection in order to provide a better record for appeal.

For the reasons stated above, claim 2 meets the requirements of § 112, second paragraph. Applicant respectfully requests the Examiner to withdraw his rejection of claim 2 under § 112.

### *Claims 3-26*

The Examiner states that “[t]he same questions of indefiniteness are also applicable with respect to claims 3-26.” (Office Action, p. 4). The logic underlying the Examiner’s rejection of these claims makes no more sense for these claims than for his rejection of claim 2. Each of these apparatus claims recites one or more structural limitations further limiting apparatus claim 1 (or an intervening claim), and, because they are apparatus claims, none recite method steps. Claims 3-26 meet the formal requirements of 35 U.S.C. § 112, second paragraph. Applicant respectfully requests the Examiner to withdraw his rejection of these claims under § 112.

### **Rejection under §§ 102 and 103**

The Examiner rejected claims 1-26 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over, any of Wall US 4,633,722 (“Wall”), Homsy et al. US 4,778,472 (“Homsy”), Morgan US 4,917,701 (“Morgan”) and Zang US 5,314,486 (“Zang”). The first portion of the Examiner’s explanation of the basis of his rejection under §§ 102 and 103 reads more like a rejection under § 112: “The term ‘adapted and configured’ is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably

apprised of the scope of the invention. . . . It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some portion of the various anatomical structures as set forth in claims 2-26.” (Office Action, p. 4).

Whether structured as a rejection under §§ 102 or 103 or as a rejection under § 112, however, the Examiner’s argument cannot stand. There is no requirement in §§ 102, 103 or 112 (or in the case law interpreting those statute sections) that a claim contain a definition for any of its terms. The term “adapted and configured” can easily be understood by a skilled artisan.

Secondly, the Examiner’s statement makes no sense in a rejection under § 102, 103 or 112: Of what (or for what) must the specification provide the standard for ascertaining a requisite degree?

Finally, even ignoring the fact that the sufficiency of the specification is not an appropriate concern in a rejection under §§ 102 or 103, a skilled artisan would indeed understand what is being claimed in claims 2-26. This portion of the Examiner’s rejection of claims 1-26 under §§ 102 and 103 does not support the rejection.

The second portion of the Examiner’s explanation of his §§ 102 and 103 rejection states that “[e]ach reference illustrates a prosthesis that includes a prosthesis body for fixation to an anatomical bone structure and an artificial joint structure carried by the prosthesis body. In each instance, the devices are capable of performing the function as broadly set forth in the claims.” (Office Action, p. 4). However, Wall, Homsy and Morgan disclose temporomandibular joint prostheses. Zang discloses a metatarso-phalangeal joint prosthesis. None of these references discloses a prosthesis system to replace a natural facet joint between adjoining inferior and superior vertebral bodies. The Examiner was not able to point to any disclosure in any of these references to support his contention that each of these prostheses could be implanted into a patient’s spine to perform the function of replacing all or a portion of the caudal and cephalad portions of a natural facet joint. In fact, none of these references has any of the specific structure recited in claim 1, such as a caudal prosthesis accommodating fixation to the inferior vertebral body at or near a pedicle and without support by a lamina and a cephalad prosthesis accommodating fixation to the superior vertebral body at or near a pedicle and without support by a lamina. This basis of the Examiner’s rejection of claims 1-26 cannot be supported either.

Finally, the Examiner has not even attempted to articulate how any of these references renders the subject matter of claims 1-26 obvious under § 103. The Examiner has therefore not met his burden of establishing the *prima facie* obviousness of those claims.

For at least these reasons, claims 1-26 are patentable over Zang, Wall, Homsy and Morgan under §§ 102 and 103. Applicant therefore respectfully requests the Examiner to withdraw the rejection of these claims.

### **Claims 27-38**

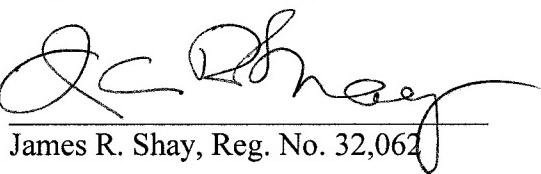
While the cover sheet of the Office Action indicates that claims 27-38 have been rejected, the body of the Office Action does not state the statutory basis for the rejection of these claims. Applicant respectfully requests the Examiner to either withdraw the rejection of these claims or state the basis of his rejection of these claims in a new non-final rejection so that Applicant will have an opportunity to respond to the rejection on the record to complete the record for appeal.

### **CONCLUSION**

For the reasons stated above, claims 1-38 meet the formal requirements of § 112. These claims are also patentable over the prior art of record. Applicant therefore requests reconsideration and allowance of claims 1-38. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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